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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|---|---|---|---|
| 09/416,267 | 10/12/99 | SU | K PF270P1 |

HM22/0627

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| EXAMINER | |
|---|---|
| PRIEBE,S | |
| **ART UNIT** | **PAPER NUMBER** |
| 1632 | 7 |

**DATE MAILED:** 06/27/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

| Office Action Summary | Application No. 09/416,267 | Applicant(s) Su et al. |
|---|---|---|
| | Examiner Scott D. Priebe, Ph.D. | Group Art Unit 1632 |

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claims**

☒ Claim(s) *1-24* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-24* are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### *Election/Restriction*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, 20 and 22, drawn to polynucleotide encoding a cytokine, vector comprising the polynucleotide, cells comprising the vector, methods of making the cells and of making the cytokine, methods of using the polynucleotide in gene therapy and diagnostics, classified in class 435, subclasses 6, 69.1, 172.3, 320.1, 325, class 514, subclass 44, and class 536, subclass 23.5.

II. Claims 14-16, drawn to a cytokine polypeptide, classified in class 530, subclass 351.

III. Claims 17 and 21, drawn to a compound which inhibits activation of a cytokine and therapeutic treatment using it, classified in class 514, subclass 1+ depending on compound.

IV. Claim 18, drawn to a compound which activates a cytokine, classified in class 514, subclass 1+ depending on compound.

V Claim 19 drawn to a method of treatment with a cytokine, classified in class 514, subclass 2.

VI. Claim 23, drawn to method for detecting a polypeptide, classified in class 435, subclass 7.1.

VII. Claim 24, drawn to a method for identifying compounds which inhibit or activate a cytokine, classified in class 435, subclass 29.

It is noted that claim 20 does not properly depend from or further limit claim 19, which recites administering a polypeptide. Administration of DNA, as in claim 20, does not constitute administration of a polypeptide as required by claim 19. DNA and polypetides are entirely different compounds.

The inventions are distinct, each from the other because of the following reasons:

Invention I and inventions II, V-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions drawn to polynucleotides and polypeptides have different functions. Polypeptides and polynucleotides are different compounds with no structural or biochemical similarities and have different biological activities and purposes. The methods of using the polypeptide, inventions V-VII, do not use the polynucleotides of invention I.

Invention II and the methods of invention I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)).

In the instant case the cytokine could be purified from tissue derived from an organism or chemically synthesized.

Inventions I and III-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions, polynucleotide encoding a cytokine, an inhibitor of the cytokine and an activator of the cytokine, have different functions and effects. The compounds have no structural or biochemical similarities.

Inventions II-IV are unrelated, each to the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions each of the compounds, a cytokine polypeptide, an inhibitor of activation and an activator, have different functions and effects. The compounds have no structural or biochemical similarities.

Inventions II and V-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides can bu used in any one of the methods of inventions V-VII.

Inventions III-IV and invention V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds of inventions III and IV can be used in the method of identifying activators and inhibitors and in a method for inhibiting or activating the action of the cytokine either in cultured cells or in an animal.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the search required for Group I is not required for Groups II-VII , restriction for examination purposes as indicated is proper, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and

1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe whose telephone number is (703) 308-7310. The examiner can normally be reached on Monday through Friday from 8 AM to 4 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasemine Chambers, can be reached on (703) 308-2035.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Scott D. Priebe, Ph.D.
Primary Examiner
Technology Center 1600
Art Unit 1632